



African Strategy for an HIV Vaccine

An outline



WHO



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WHO-UNAIDS HIV Vaccine Initiative
Geneva, Switzerland, 2000

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Summary

HIV/AIDS has emerged as the leading cause of death in Africa, and a safe, highly effective, affordable and accessible HIV preventive vaccine offers the best long-term hope to control the epidemic.

A proactive participation of African scientists, institutions and the community will be necessary in order to ensure that appropriate HIV vaccines are developed for Africa. To that effect the **African Strategy for an HIV Vaccine** has been developed, to advocate and support a coordinated African effort to contribute to the global HIV vaccine development goals, ensuring that appropriate and affordable vaccines are developed for Africa in the shortest possible time.

The **African Strategy for an HIV Vaccine** is based on the principles of inclusiveness, transparency and collaboration, as a long-term effort based on capacity building, promoting research with the utmost respect for human rights, aspiring to the highest ethical and scientific standards, and with full community participation. It promotes simultaneous development and evaluation of different candidate vaccines, as an international public good.

The **African Strategy for an HIV Vaccine** aims at facilitating the conduct of research and clinical trials, with the target of completing at least one large-scale phase III trial by 2007.

The **African Strategy for an HIV Vaccine** defines a framework for activities in the following areas:

- Advocacy, information and education
- Guidance and coordination
- Promotion of appropriate candidate vaccines
- Facilitation of trials through capacity building
- Future access

The framework of activities is being translated into a specific action plan, with indicators and budget, which will be presented to the international donor community and research agencies, for support and collaboration.

A. Preamble

A consultation to discuss strategies to accelerate the development of HIV vaccines in Africa was convened in Nairobi, Kenya, on 12-14 June 2000, under the auspices of the World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Southern Africa Development Community (SADC), the Society for AIDS in Africa (SAA) and the African Council of AIDS Service Organization (AfriCASO). The consultation was attended by 40 participants from 15 African countries and representatives from the sponsoring organizations.

The major outcomes of the meetings were:

1. **The Nairobi Declaration: An African Appeal for an HIV Vaccine**, a policy/advocacy document urging major stakeholders in Africa and elsewhere to support activities aimed at accelerating the development of HIV vaccines in Africa, and
2. The **African Strategy for an HIV Vaccine: an outline**, described in the present document.

The development and implementation of the **African Strategy for an HIV vaccine** will be an evolving process, and it will be revised and refined periodically. Specific activities will be identified, prioritized and implemented through consultations and collaboration with multiple partners, in and outside Africa.

B. Situation Analysis

- Two decades into the HIV pandemic, sub-Saharan Africa continues to bear a disproportionate burden of HIV infection. Two-thirds of all people with HIV/AIDS live in sub-Saharan Africa. In fifteen African countries, 10% or more of the adult population is already infected with HIV.
- Whilst most countries in sub-Saharan Africa have established National AIDS Control Programmes, interventions such as behaviour modification, condom promotion and treatment of other sexually transmitted infections have not been sufficient to significantly reduce the incidence of HIV infections. From the estimated 15 000 new HIV infections occurring every day in the world, 70 % occur in sub-Saharan Africa.
- Whilst efforts to promote known interventions for HIV prevention must be strengthened, preventive HIV vaccines remain the best long-term solution to control the HIV pandemic.
- Global HIV vaccine efforts have started to receive renewed interest in the past three years, and much progress has been made, including the development of potentially more immunogenic candidate vaccines. Multiple clinical trials of HIV candidate vaccines will have to be conducted simultaneously, to assess the safety, immunogenicity and protective efficacy of different vaccine concepts, against different HIV-1 subtypes, and in different populations.
- Whilst the vaccinological implications of different HIV-1 genetic subtypes remain unresolved, there is consensus that given the current stage of HIV vaccine research and development, efforts should be made to develop candidate vaccines based on HIV-1 subtypes prevalent in different regions in Africa. It is also recognized that HIV-2 candidate vaccines are not available at the present time.

- Although several African countries have participated in different international collaborative projects, including other HIV prevention trials, infrastructures and capabilities to conduct HIV vaccine trials are virtually non-existent in Africa.
- It is also recognized that the proactive participation of African scientists, institutions and the community will be necessary in order to ensure that appropriate HIV vaccines are developed for Africa. This will require addressing market failures and other factors that may act as disincentives to developing vaccines for Africa. Fortunately, anecdotal evidence suggests that there are high levels of government and community acceptance of and interest in HIV vaccines.

C. Response Analysis

1. **Political commitment:** Several countries (e.g. Botswana, Ethiopia, Kenya, South Africa, and Uganda) have demonstrated high-level political support for HIV vaccine research and development, as evidenced by action plans and the allocation of resources.
2. **Advocacy:** Different international (e.g. WHO, UNAIDS, GAVI, IAVI) and regional organizations (e.g. SADC, OAU, AfriCASO, SWAA, SAA) have already been engaging governments and communities at the local, regional and international level to fast-track HIV vaccine development efforts in Africa.
3. **Coordination and collaboration:** Whilst some international networking has been taking place (e.g. through NIH-funded projects), coordination and collaboration within Africa and with international agencies and organizations is limited and must be improved.
4. **Resources (human, material and financial):** Although some governments (e.g. South Africa, Uganda) and international agencies (e.g. NIH, WHO-UNAIDS, EU, ANRS, CDC, JICA, Sida/SAREC, IAVI) have provided support to vaccine-related activities in Africa, the level has been insufficient to achieve any significant results.
5. **Capacity building:** Although HIV vaccine trials in Africa could significantly contribute to the global effort to develop HIV vaccines, the capacity to conduct these trials is very limited and needs to be substantially strengthened.

In general, whilst there have been some isolated efforts to conduct HIV vaccine research in Africa, it is recognized that there is a need to significantly increase and strengthen these efforts, to fast-track the HIV vaccine development effort in Africa.

D. Vision and Goals

The African Strategy for an HIV Vaccine advocates and supports a coordinated effort to contribute to the global HIV vaccine development goals, ensuring that appropriate and affordable vaccines are developed for Africa in the shortest possible time.

E. Principles

The **African Strategy for an HIV Vaccine** will:

1. Include all countries in the African region (although not all countries in the region will need to conduct vaccine trials, it is essential that all are fully informed and supportive of the overall effort).
2. Be coordinated with other ongoing national and regional HIV prevention efforts, and with the International Partnership Against AIDS in Africa (IPAA).
3. Serve as a transparent collaborative process, with equitable participation of multiple partners from the public and private sectors, from countries in the region and from the international community.
4. Be developed as a long-term and sustainable effort, based on capacity building.
5. Promote research with the utmost respect for human rights.
6. Aspire to the highest ethical and scientific standards.
7. Ensure full community participation.
8. Promote parallel development and evaluation of different candidate vaccines, focusing on those deemed more appropriate for the region
9. Contribute to the development of HIV vaccines, consistent with the concept of an international public good.

F. Strategic Milestone

The **African Strategy for an HIV Vaccine** will fast-track HIV vaccine development by advocating and working towards ensuring that by:

1. 2002 - Appropriate preventive candidate vaccines based on virus subtypes prevalent in different regions in Africa are available.
2. 2003 - At least four phase I/II (safety and immunogenicity) trials are completed.
3. 2004 - At least one phase III (efficacy) trial is initiated.
4. 2006 - Specific plans to make a future HIV vaccine available in Africa are developed.
5. 2007 - At least one phase III trial is completed.

Promising candidate vaccines being developed and evaluated elsewhere could be considered for adaptation to African subtypes, especially after successful completion of efficacy trials. Fast-tracking such candidate vaccines could reduce the timeframe described above.

G. Activities Framework

To achieve the above strategic milestones a number of activities will be implemented in the following areas (as defined by the WHO-UNAIDS Global HIV Vaccine Strategy):

1. Advocacy, information and education

- Adopt a multisectoral approach, targeting national, regional and international stakeholders, in both the public and private sectors, including international organizations and bilateral donor agencies and countries.
- Sensitize politicians, religious leaders, NGOs, professional groups, media and the public at large, portraying HIV/AIDS as a health, security, developmental and economic issue.
- Develop information/communication “packages” and approaches appropriate for the different audiences, providing specific information on how the various parties can support the vaccine initiative.
- Advocate for the African HIV Vaccine Initiative to be included in the National HIV/AIDS Strategic Plans.

2. Guidance and coordination

- Establish a coordinating mechanism (or Steering Committee) for the African HIV Vaccine Initiative.
- Establish subgroups or task forces in different areas (e.g. science, resource mobilization, ethics, advocacy and communications).
- Network people working in different areas relevant to HIV vaccine development, strengthening existing networks (e.g. the Society of AIDS in Africa, the African AIDS Research Network).
- Develop, when appropriate, National AIDS Vaccine Plans and/or Strategies, to coordinate HIV vaccine activities within individual countries.
- Develop general guidelines in relevant areas (e.g. ethics, conduct of clinical trials, communication, community participation).
- Establish linkages with WHO-UNAIDS for technical and financial support, and to facilitate access to relevant international agencies and bodies.

3. Promotion of appropriate candidate vaccines

- Prioritize the development of preventive vaccines but also consider, when appropriate, therapeutic vaccines and vaccines to prevent vertical transmission.
- Ensure that countries intending to select candidate vaccines for testing have appropriate and competent regulatory authorities (WHO-UNAIDS can be approached for advice and independent evaluation).
- Continue monitoring the distribution of HIV-1 subtypes in Africa (including genetic, biological and immunological characterization) to select strains to be used in the manufacturing of candidate vaccines, to match trial populations with candidate vaccines, to interpret results of clinical trials, and to obtain information which could be relevant to decide how and where to use future effective vaccines.

- Support research to understand the immunological/vaccine relevance of the HIV-1 genetic subtypes.
- Explore, through international collaboration, approaches for the development of broadly effective (global) vaccines, as this would be of benefit to Africa and the rest of the world, and encourage industrial investment.
- Train African scientists in methods relevant to vaccine development and monitoring.
- Identify and support opportunities for a local contribution to the process of candidate vaccine development (e.g. the South African AIDS Vaccine Initiative), including possibilities for GMP (Good Manufacturing Practices) production.

4. Facilitation of trials through capacity building¹

- Establish an inventory of existing resources, identifying strengths and weaknesses, and plan for training and capacity building.
- Identify and strengthen infrastructures essential for the conduct of HIV vaccine trials (e.g. national and regional centres of excellence; scientific, legal and ethical frameworks for protocol review).
- Ensure at least one vaccine evaluation site per region.
- Establish/strengthen laboratory facilities to a GLP (Good Laboratory Practices) level: virology; immunology; specimen repositories; specimen handling, transport, storage and management.
- Establish/strengthen clinical trial facilities to GCP (Good Clinical Practices) level: phase I-III trials training.
- Establish/strengthen epidemiological capacity, including cohort development and data management (biostatistics, quality assurance, data analysis).
- Establish/strengthen legal frameworks and ethical and scientific review mechanisms.
- Develop capacity to conduct vaccine-related social behavioural research (e.g. monitoring behaviour among trial participants, informed consent and counselling, willingness to participate and acceptability of trials, social risk factors, social implications of trial participation).
- Establish Data and Safety Monitoring Boards (DSMB).
- Provide training on writing grant applications and scientific papers.
- Build general management capacity, including expertise to negotiate technology transfer agreements, to understand intellectual property and licensing issues, and to deal with the economic aspect of trial and post-trial costs.
- Develop meaningful community support and participation through advocacy and lobbying and by the establishment of appropriate Community Advisory Boards, to serve as links between community/potential volunteers and scientists.

¹ Capacity building is the sum of efforts needed to nurture, enhance and utilize the skills and capabilities of people and institutions at all levels, so that they can better progress towards sustainable development. At the basic conceptual level, building capacity is about empowering people and organizations to solve their problems, rather than attempting to fix those problems directly. When capacity building is successful, the result is more effective people and institutions better able to provide products and services on a sustainable basis (UNDP).

5. Future access

- Develop plans and strategies on how to use future vaccines.
- Explore mechanisms to finance future vaccine procurement, including partnerships with governments and vaccine manufacturers.
- Take steps to ensure vaccine access at the completion of trials, in conformity with the ethical principle of distributive justice.
- Consider mechanisms to ensure the contribution of African Governments to a future vaccine purchase fund.

H. Next steps

1. July 2000: Discuss the outline of the **African Strategy for an HIV Vaccine** at the XIII International AIDS Conference (Durban, South Africa, 9-14 July 2000).
2. July-November 2000: Develop a detailed Plan of Action (with specific activities, indicators, and budget) in close consultation with all relevant stakeholders.
3. December 2000 or early 2001: Present the Plan of Action to the donor community and to the international collaborators, for technical and financial support.
4. During the process **The Nairobi Declaration: An African Appeal for an HIV Vaccine** will be used to seek political support from relevant agencies and bodies.

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